

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

### **REMARKS**

Claims 1-3, 8-10, 18-20, and 38-49 are pending.

Claims 8, 9, 38, 39 and 45-49 are allowed.

Claims 1, 2, 18-20, 42, and 43 stand rejected.

Claims 3, 10, 19, 20, 40, and 41 are objected to.

Applicants acknowledge the Examiner's rejection of claims 3, 10, 19, 20, 40, 41 and 44 under 37 C.F.R. § 1.75(c) for alleged improper dependent form. Applicants respectfully traverse these objections, for which there is no basis.

Applicants acknowledge the Examiner's rejection of claims 19 and 20, under 35 U.S.C. § 102(e), as allegedly being anticipated by Doherty-II (U.S. 6,414,130). Applicants respectfully traverse this rejection.

The Examiner maintained the rejection of claims 1, 2, 18-20, 42, and 43, under 35 U.S.C. § 112 first paragraph, as allegedly comprising new matter in view of the recitation of SEQ ID NOS having respective particular polymorphic amino acid positions. Applicant respectfully traverses this rejection and has provided appropriate rebuttal argument.

No new matter has been added.

### ***Claim Objections***

The Examiner objected to claims 3, 10, 19, 20, 40, and 41 under 37 C.F.R. § 1.75(c) for alleged improper dependent form. Applicants respectfully traverse these objections, for which there is no basis.

Specifically, the subject claims (as recognized by the Examiner's statements at the top of page 11 of the present Office Action), are drawn to a polypeptide comprising the entire sequence of SEQ ID NOS:14 and 19-28 (claim 3) or SEQ ID NOS:15 and 29-38 (claim 10) where the claims

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

inherently include all of any one of these sequences as the C-terminal 79 contiguous amino acids. Claims 8 and 10 are, therefore, proper dependent claims, because these sequences include the respective recited residues and represent a more limited sequence group (entire sequence of SEQ ID NOS:14 and 19-28 (claim 3) or SEQ ID NOS:15 and 29-38). Likewise for dependent claims 19, 20, 40 and 41, where there is no need to repeat recitation of the fragments limitations that are already recited in independent claim 18, and thus imputed to the dependent claims.

Applicants, have nonetheless, amended independent claims 1, 8 and 18 to clarify the subject matter, where SEQ ID NOS:14 and 19-28 and SEQ ID NOS:15 and 29-38 are specific, defined sequences.

Applicants, therefore, respectfully request withdrawal of this rejection.

#### ***Rejections under 35 USC § 102***

The Examiner rejected claims 19 and 20, under 35 U.S.C. § 102(e), as allegedly being anticipated by Doherty-II (U.S. 6,414,130).

Specifically, the Examiner states that these claims claim subject matter outside the scope of claim 18 that overlap with Doherty-II

Applicants respectfully traverse this rejection, because claims 19 and 20 depend from independent claim 18, such that the fragments recited in claims 19 and 20 *must* contain the limits of the fragments recited in independent claim 18.

Applicants, therefore, respectfully request withdrawal of this rejection.

#### ***Rejections under 35 USC § 112***

The Examiner Has maintained the rejection of claims 1, 2, 18, 42, and 43, under 35 U.S.C. 112 first paragraph, as allegedly failing to comply with the written description requirement (i.e.,

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

new matter) in view of the recitation of “wherein the polypeptide comprises: with respect to SEQ ID NO:14, at least one of the position 6 Pro and the position 73 Asp; with respect to SEQ ID NO:19, the position 2 Ser; with respect to SEQ ID NO:20, the position 5 Pro; with respect to SEQ ID NO:21, both the position 6 Leu and the position 73 Asp; with respect to SEQ ID NO:22, the position 16 Gln; with respect to SEQ ID NO:23, the position 18 Leu; with respect to SEQ ID NO:24, the position 21 Asp, Ala or Val; with respect to SEQ ID NO:25, the position 36 Ile; with respect to SEQ ID NO:26, the position 54 Arg; with respect to SEQ ID NO:27, the position 64 Leu; or with respect to SEQ ID NO:28, both the position 6 Pro and the position 73 Asn.”

Applicants respectfully reassert and reapply Applicants’ arguments of record as follows hereunder.

The Examiner states that “it is noted that the rejection of the claims is not based on the finding that the specification fails to teach polypeptides that comprise the fragments as recited in the claims,” and rather that “the current set of claims is an attempt to carve out a patentable portion of what is broadly disclosed in the specification.” The Examiner states that “the specification discloses the sequences that are the polymorphisms of the previously disclosed Herstatin sequence,” and further discloses “polypeptides that comprise any 50 to 79 contiguous amino acids from these sequences, where the polypeptides bind to the ECD of HER-2 with an affinity binding constant of  $10^8 \text{M}^{-1}$ .” The Examiner states, however, that “the specification fails to provide support for the limitation that the fragments must comprise the residues that are different from the previously disclosed Herstatin sequence” implying a “negative limitation,” and that “by reciting limitations that require the claimed polypeptides that require a specific residue from a sequence, the claims are excluding fragments of 50 to 79 amino acids in length that are the same as fragments of 50 to 79 amino acids in length that have already been disclosed in the prior art (U.S. 7,393,823).” Based on this, the Examiner concludes “thus, the claims imply a negative limitation or an exclusionary

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

proviso” and that MPEP 2173.05(i) states that any negative limitation or proviso must have a basis in the original disclosure,” and that while applicants “while presenting evidence that the claimed polypeptides with respect to the polypeptides comprising the recited fragments are encompassed by the teachings of the specification, fail to provide support or a new genus of polypeptides that has been carved away from the originally disclosed genus.”

Applicants respectfully traverse the Examiner’s rejection based on the fact that the Applicants’ above-described recitation is not a proviso clause, and even it is was, the Examiner, by her own acknowledgment, has misconstrued MPEP 2173.05(i) and U.S. patent law with respect to proviso clauses. Additionally, contrary to the Examiner’s urging, there is ample support for the present claims, which claim less than the full scope of the disclosure.

**First**, contrary to the Examiner’s urging, Applicants respectfully point out that there is nothing in U.S. patent law that prohibits an applicant to “carve out” a patentable portion of what is disclosed in the specification. Applicant is entitled to claim less than the full scope of the disclosure (see., e.g., In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) discussed below; and see also In re Wertheim, 191 USPQ 90, 97 (CCPA, 1976); and In re Saunders 170 USPQ 213, 220 (1971)), cited and discussed in the opinion of In re Johnson. We agree, however, that the original disclosure must provide support for any claims, including claims claiming less than the full scope of the disclosure

**Second**, Applicants point out that while the presently claimed genus (e.g., claim 1) may be *smaller* than that of original submitted claim 1, the claims as presently presented do not recite a negative limitation or proviso clause. Rather the claims are drawn to a smaller genus than was originally claims, but where such smaller genus of polypeptides is fully supported, as discussed herein below, and for reasons already of record in Applicants’ last Response and Amendment, that are reaffirmed and reasserted herein, and where the Examiner has moreover acknowledged based on

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

this evidence that "the rejection is not based on the finding that the specification fails to teach polypeptides that comprise the fragments as recited in the claims."

*Third*, even were one to accept the Examiner's implication of a negative limitation or proviso clause into Applicants' presently claimed subject matter, contrary to the Examiner's urging, any such implied negative limitation or an exclusionary proviso has more than sufficient support in the original disclosure under 35 U.S.C. 112 first paragraph and MPEP 2173.05(i) (Negative Limitations) (cited by the Examiner), and according to U.S. case law specifically cited in MPEP 2173.05(i). Specifically, according to MPEP 2173.05(i), and as recognized by the Examiner:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

MPEP 2173.05(i) (emphasis added). The Examiner's contention in the instant case is *contrary* to the holding and opinion *In re Johnson*, cited in MPEP 2173.05(i).

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

Applicants reassert *In re Johnson*, which despite being discussed in detail in Applicants' last Response and Amendment, was not significantly addressed, and presumably, therefore, not sufficiently considered by the Examiner in the present Office Action. The Examiner acknowledges (at the top of page 6 of the present Office Action) that "literal support" is not required, but that any negative limitations or proviso must have a basis in the original specification. The Examiner also acknowledges Applicants' original Table 1 explicitly describing the polymorphic positions currently being pursued in Applicants' pending claims, along with previously claimed variant 11 (U.S. 7,393,823).

***In re Johnson.*** *In re Johnson* (*already of record*) was an appeal from a decision of the Patent and Trademark Office Board of Appeals affirming, *inter alia*, a 35 U.S.C. 112 first paragraph written description rejection, based on alleged new matter in view of recitation of particular proviso clauses in claims drawn to a chemical genus of thermoplastic polyarylene polyether polymers. Specifically, with respect to alleged new matter, the substituent definitions of the genus claims at issue were amended to recite provisos that substituents E and E' may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei. The Board of Appeals had concluded that the "artificial subgenus" thus created in the claims was not described in the parent case<sup>1</sup> and would be new matter if introduced into the parent case, and would thus equally constitute "new matter," to the present application for which no antecedent basis existed in the parent case (*Id* at bottom of page 192).

The CCPA *reversed* this Board's of Appeals conclusion despite the fact that such proviso clauses were not present in the original applications at issue (see discussion under "*II*" on page 195). Specifically, the appellate court found "more than ample basis for claims of such scope" the

---

<sup>1</sup> In *re Johnson* involved an interference proceeding wherein the question of granting priority to a parent case was at issue.

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

opinion stating that the disclosure was clearly directed to polymers of the type claimed, that fifty specific choices (e.g., species) were mentioned for the E precursor compound, that a broad *class* was identified as embracing suitable *choices* for the E' precursor compound, that twenty-six "examples" were disclosed which detailed fifteen species of polyarylene polyethers, that only fourteen of those species and twenty-three of the "examples" were within the scope of the claims on appeal, and that two of the many choices for E and E' precursor compounds are deleted from the protection sought, "because appellant is *claiming less* than the full scope of his disclosure." The opinion, at page 195, goes on to state "But, as we said in *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976): Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. **It is for the inventor to decide what bounds of protection he will seek.** In *re Saunders*, 58 CCPA 1316, 1327, 444 F.2d 599, 607, 170 USPQ 213, 220 (1971)." The opinion further states that "The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count." Finally, the opinion concludes "Here, as we hold on the facts of this case, the 'written description' in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining. The facts of the prosecution are properly presented and relied on, under these circumstances, to indicate that appellants are merely excising the invention of another, to which they are not entitled, and are not creating an 'artificial subgenus' or claiming 'new matter.' "

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

*The instant application.* The facts of the instant case are analogous to those of In re Johnson discussed above. The Examiner acknowledges that the specification teaches polypeptides that comprise the fragments as recited in the claims. The Specification also teaches the specific polypeptides recited in the instant claims—because it teaches fragments comprising 50-79 amino acids of the ECDIIIa domain, as well as teaching the precise variant residues claimed and the precise locations of those claimed variants, such that it is explicitly clear that ALL polymorphic variant residue-containing polypeptides comprising 50-79 amino acids of the ECDIIIa domain are disclosed and encompassed by Applicants' original conception. The specification provides ample basis for claims of the instant scope as the specification/disclosure is clearly directed to polypeptides of the type claimed, where many specific choices (e.g., species) are disclosed for the polymorphic polypeptide (see Applicants' Table 1), where a broad *class* was identified that not only encompasses, as recognized by the Examiner, but also specifically includes the claimed polymorphic species, and that some of the many choices for the originally disclosed polypeptides are not instantly present in the protection sought, **"because, as entitled under relevant U.S. patent law, appellant is claiming less than the full scope of the disclosure."**

As stated under MPEP 2173.05(i), a lack of literal basis in the specification for a negative limitation is not sufficient to establish a *prima facie* case for lack of descriptive support. Applicants contend that, as recognized and acknowledged by the Examiner, that the originally filed disclosure would have conveyed the claimed polypeptide species to one of ordinary skill in the art. ECDIIIa variant containing polypeptides, both comprising the ECDIIIa or sub fragments thereof are indeed encompassed within the original specification teachings. The independent claims have merely been amended to delineate the variant residues, including subfragment residues. Support for this amendment is indeed found (both explicitly and implicitly) in Table 1 on page 33 of the originally-

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

filed specification (see also, for example, original claim 27 reciting “ECDIIIa variant sequence”). Additionally, the specification recites that “[t]his result demonstrates that in the human population there are several variations in the intron-8 encoded domain that could lead to altered biochemical and biological properties among ECDIIIa-containing protein variants” (page 32, lines 21-23). Additionally, the specification at page 14, lines 6-8, recites “[f]or the production of antibodies, various host animals may be immunized by injection with *e.g.*, polyhistidine-tagged ECDIIIa variant polypeptides, truncated ECDIIIa variant polypeptides, functional equivalents of the ECDIIIa variants or mutants of the ECDIIIa region.” In this regard, Applicants fail to understand how the Examiner can support the statement at page 9 of the present Office Action that “methods of making antibodies using variant or mutants of the ECDIIIa region” are “irrelevant” to the present question. It is relevant, because the specification teaches “truncated ECDIIIa variant polypeptides”, where the specification teaches the specific polypeptides recited in the instant claims—because it teaches fragments comprising 50-79 amino acids of the ECDIIIa domain, as well as teaching the precise variant residues claimed and the precise locations of those claimed variants, such that it is explicitly clear that ALL polymorphic variant residue-containing polypeptides comprising 50-79 amino acids of the ECDIIIa domain are disclosed and encompassed by Applicants’ original conception, and further that it is particularly the variant comprising polypeptides and fragments comprising same that that are being newly disclosed and pursued in Applicants’ specification.

Additionally, the specification teaches that “PCR, or reverse transcription can be utilized to identify nucleotide variation within the ECDIIIa domain” (page 17, lines 19-20). Additionally, as stated in Dr. Gail Clinton’s Declaration of record (see page 5, paragraph 5, of Declaration of Dr. Gail Clinton 19 April 2003, of record in this case), “[t]he discovery of these novel polymorphisms was precisely the reason that the present application was filed. The Herstatin sequence of the earlier U.S. patent application (09/234,208; now U.S. 7,393,823) was already disclosed and claimed

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

in that application, and it was the primary purpose of the present application to claim additional polymorphisms, while not claiming the previously claimed Herstatin. In Example 11 of the present application, the 1999 Doherty et al. PNAS paper (which lists the previously claimed Herstatin) was cited in the introduction. Example 11 then goes on to describe the additional, different polymorphisms by their nucleotide and deduced amino acid sequence. These additional variations in the intron-8 encoded domain were discovered in the human population and Table 1 sets forth those variants, including originally identified variant 11. Said another way, while Table 1 of Example 11 lists the Doherty et al sequence as variant 11 along with the additional polymorphisms (variants 1-10), the purpose of the table is to set forth and summarize additional variants of the intron-8 encoded domain that had been discovered to the time of the filing of this patent application.” The specification, therefore, discloses new polymorphic variants and ECDIIIa variant fragments of about 50 to about 79 amino acids. For example, the specification teaches ECDIIIa subfragments and teaches variants with the subfragment region. It would be an absurdity to construe the facts such that Applicants would not be entitled to claim a subfragment comprising any of the variant amino acids disclosed. Applicants are the first to describe such variants and this was precisely why the present application was filed, as declared by the Applicants, and there is ample written description for the presently amended claims.

Applicants respectfully contend that given the teachings of the specification, the Examiner's position is unsupported, is inconsistent with the facts, inconsistent with MPEP 2173.05(i), and contrary to relevant U.S. case law on this issue, including that of *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977), cited in MPEP 2173.05(i), and other references cited therein.

The Examiner states, at page 8 of the present Office Action, that Applicants' amendment “does not merely delineate the variant residues, but instead changes the scope of the genus of

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

fragments of SEQ ID NO:14 of about 50-79 contiguous residues in length.” Applicants respectfully point out that changing the scope of a patent claim by amendment is proper, as it is here, where there is support to do so.

The Examiner states, at page 8 of the present Office Action, that “Table 1 provides the sequence information for the variants of ECDIII polypeptides, but does not describe the genus of fragments of 50 to 70 amino acids in length, nor does it describe the subset of fragments of about 50 to 79 amino acids in length that must comprise the positions as set forth in the claims.” Applicants respectfully point out that that Table 1 in combination with the original claims, sequences and Sequence Listing provides the herstatin sequence and polymorphic positions and variant amino acids, and thus provides support for all fragments claimed including those presently claimed.

The Examiner states, at Page 10 of the present Office Action, that the limitation in the present case is unlike that of *In re Johnson* because “in Johnson, specifically named species were excluded to make a new genus, whereas in the claims of the present application, a subgenus is excluded to make a new genus.” Applicants respectfully disagree that the present case is unlike that of Johnson. In both cases less than the full scope of what was originally disclosed is being claimed by claiming a subgenus. Applicants amendments are fully supported by *In re Johnson*, where as in Johnson, Applicants’ original specification provides ample support for the amendments.

Applicants respectfully point out that the Examiner’s position is analogous to that of the underlying Patent and Trademark Office Board of Appeals that was overruled by *In re Johnson*. As stated in *In re Johnson*, the “The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.” Finally, the opinion concludes “Here, as we hold on the facts of this case, the ‘written description’ in the 1963 specification supported the claims in the absence of the limitation, and that specification, having described the whole, necessarily described the part remaining.

### **Purdue and In re Welstead**

By distinguishing *In re Johnson* the Examiner suggests that a subgenus is excluded and a new genus is made. Nothing in patent case law suggests that a new genus cannot be claimed as long as there is support in the application as filed. The Examiner, then invited Applicants to review *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481 (Fed. Cir. 2000) (*Purdue*, hereinafter) and *In re Welstead*, 174 USPQ 449 (CCPA 1972) (*Welstead*, hereinafter). By citing the above case law, it appears that the Examiner is attempting to support her assertion that one cannot claim a smaller part of an invention than had been originally claimed. (Applicants submit that this, in fact, happens in most cases prosecuted with the USPTO.) Instead, however, Applicants submit that both cases show that when carving out patentable portion of what is disclosed in the specification, one must take care to not carve so much as to remove it from the reach of written descriptive support. Both *Purdue* and *Welstead* concern the sufficiency of written description for the new claim limitations introduced, and in both cases, as recognized by the Examiner, the respective courts determined that the application as filed did not contain specific enough written description to support the newly limited claims. Both these cases are, however, distinguishable from the current situation and specification. In the instant case, Applicants contend that the alleged ‘carving out’ as well as what is remaining after the alleged ‘carving out’ is completely supported and sufficiently explained by the specification. A key guidepost that exists in the specification is Applicants’ Table 1.

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

**Purdue.** *Purdue* was an appeal to the U.S. Court of Appeals, Federal Circuit from the U.S. District Court for the District of Delaware. In *Purdue*, “the trial court considered “whether the limitation ‘a maximum plasma concentration ( $C_{\max}$ ) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form [C<sub>24</sub>]’ was **adequately described** in the original disclosure of the ’688 application as originally filed. The trial court found that it was **not.**” *Purdue* at 1483, *emphasis added*. By finding that the original application did not support the amended claims, the trial court invalidated Purdue Pharma’s ’360 patent. Purdue Pharma asserted “that the district court made various legal errors in its analysis of the written description issue and that its factual finding ... was clearly erroneous.” *Id* at 1483. The appellate court in this case went on to affirm the trial court, stating “we conclude that the court’s finding on the written description issue did not constitute clear error.” *Id* at 1483.

Specifically, at issue was what exactly is considered written description under 35 U.S.C. § 112. The court in *Purdue* stated that the written description requirement need not “provide *in haec verba* [i.e., exact language; literal] support for the claimed subject matter.” *Id* at 1483. Even so, the disclosure “must ... convey with reasonable clarity to those skilled in the art that ...[the inventor] was in possession of the invention.” *Id* at 1483, quoting *Vas-Cath Inc. v. Murhkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

Reasoning that Purdue Pharma had not met the written description requirement the court stated, “what the ’360 patentees have done is to pick a characteristic possessed by two of their formulations, a characteristic that is not discussed even in passing in the disclosure, and then make it the basis of claims that cover not just those two formulations, but any formulation that has that characteristic.” *Purdue* at 1487. Applicants present situation is clearly distinguished from that of Purdue Pharma, because Applicants describe all fragments in the original specification, including those presently claimed, and Table 1 supports the specific subgenus claimed, and Applicants

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

therefore contend that not only does the originally filed application clearly and adequately discuss the new claim limitations, but those claim limitations have always been an integral and important part of the Applicants' invention, as evidenced by the Table 1.

**In re Welstead.** *In re Welstead*, dealing with chemical genera, was an appeal to the CCPA from a decision of the Patent Office Board of Appeals, which affirmed the rejection of patent claim 23. At issue was the assertion by the Examiner in the case that the Applicant had introduced new matter into the claim when the claim was amended. The Examiner specifically "stated that the amended form of the claim 'fails to find basis in the disclosure as originally filed' and that '[t]he genus grouping as now appears in claim 23, while more specific, is ... a new grouping'". *Welstead* at 450.

The Board of Appeals affirmed the Examiner's rejection and stated (somewhat confusingly) "[w]e conclude that the limitation of claim 23 had the effect of arbitrarily designating a group of materials subgeneric to the group previously claimed, which was not **delineated** or **supported** as such in the original application." *Id.* At 450, *emphasis added*.

The CCPA affirmed the Board's decision stating "we agree with the solicitor that we should reverse only if appellant were to persuade us that that the amended claim ... defined a genus ... which was itself described in the application as filed. .... Since the specification as filed contained neither a description as such of the genus ... nor descriptions of the species thereof amounting, in the aggregate, to the same thing, the rejection of claim 23 as drawn to new matter is affirmed." *Id.* at 451. *Welstead* is clearly distinguishable from the current application, because Applicants describe all fragments in the original specification, including those presently claimed, and Table 1 supports the specific subgenus claimed, and Applicants therefore contend that not only does the originally filed application clearly and adequately discuss the new claim limitations, but those claim

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

limitations have always been an integral and important part of the Applicants' invention, as evidenced by the Table 1.

In conclusion, even if one implies a negative limitation or proviso clause as urged by the Examiner, there is no requirement under U.S. patent law to have a "literal basis" for such negative limitation or proviso clause. There is no requirement, contrary to the Examiner's urging, under U.S. Patent law that the specification provide "literal support" for a limitation that the fragments must comprise the residues that are different from the previously disclosed Herstatin. Even if there were, the specification does provide such literal support, and nonetheless provides adequate support. The specification not only teaches polypeptides that comprise the fragments as recited in the claims, but also teaches the specific polypeptides recited in the instant claims. Therefore, under *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977), and the MPEP 2173.05(i) the specification provides more than ample support for any such implied negative limitation or proviso. In any event, Applicants are in fact entitled to "carve out" a portion of the disclosed subject matter, whether it be done by merely claiming a portion of the invention, or through a negative limitation or proviso clause.

Applicants, therefore, respectfully request reconsideration and withdrawal of the Examiner's alleged new matter rejection.

#### ***Objection to Claim 44***

Claim 44 was objected to for depending from a rejected claims. Claim 44 depends from claim 42, which Applicants respectfully contend is allowable as presently amended.

Applicants respectfully contend that all claims are allowable as presented herein.

Application No.: 09/506,079  
Attorney Docket No.: 49321-16  
First Applicant's Name: Gail M. Clinton  
Application Filing Date: February 16, 2000  
Office Action Dated: 23 September 2008  
Date of Response: 23 March 2009  
Examiner: Anne L. Holleran

### ***CONCLUSION***

In view of the foregoing amendments and remarks, Applicants respectfully request entry of the present Amendment and allowance of all claims as provided herein above. The Examiner is encouraged to phone Applicants' attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

Davis Wright Tremaine LLP  
1201 Third Avenue, Suite 2200  
Seattle, Washington 98101-3045  
Telephone: 206-757-8023  
Facsimile: 206-757-7023

Respectfully submitted,  
Gail M. Clinton et al.  
Davis Wright Tremaine LLP

/Barry L. Davison, Ph.D., J.D./  
Barry L. Davison, Ph.D., J.D.  
Attorney for Applicant  
Registration No. 47,309